

# Step-by-Step Instructions for the Export Listing Module (ELM)

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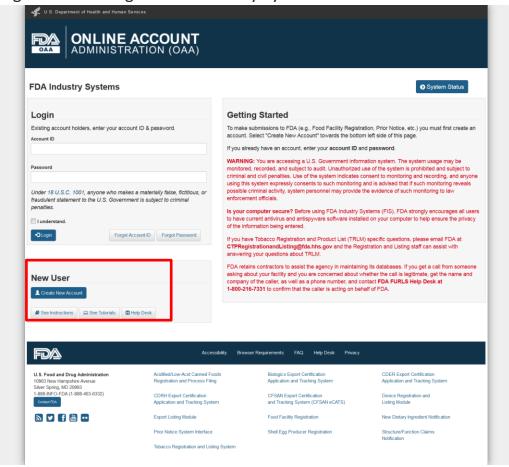
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# Accessing the Export Listing Module (ELM)

Figure 1: Creating an FDA Industry Systems Account



The Export Listing Module (ELM) is an FDA Industry System (FIS) and can be accessed via https://www.access.fda.gov/. If you do not have an existing FIS account, click on the "Create New Account" button to create one. This will take you to the Create New Account screen where you may select the center and the systems you will need to access.

NOTE: You may wish to create a single enterprise account for all FDA submissions related to your facility and to create subaccounts for personnel that will manage submissions to FDA. All submissions by subaccounts will be accessible via the enterprise FIS account, which will allow continued access to previous submissions in the event that an employee leaves the facility. For more information on account management, please visit review the FDA Industry Systems User Guide: Account Management.

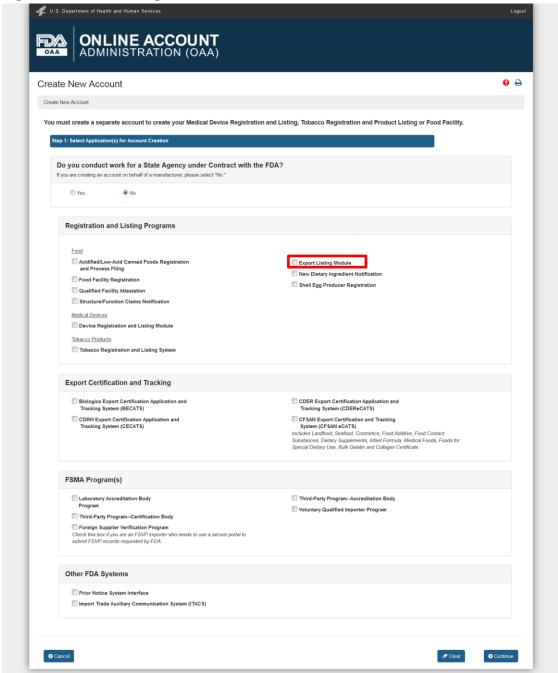
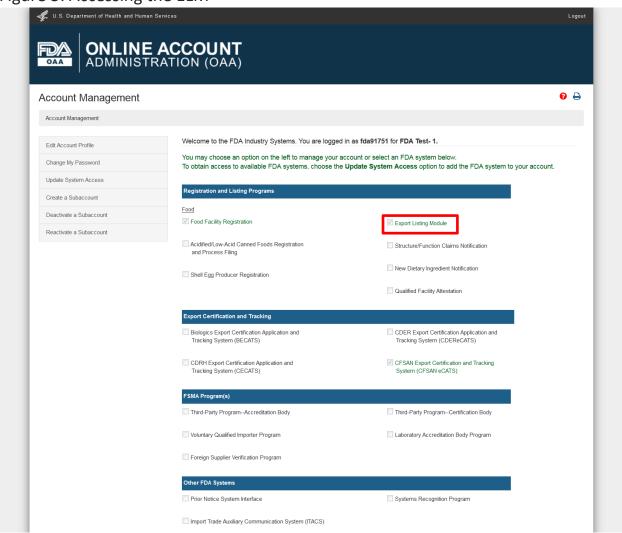


Figure 2: Establishing Access to the ELM for New Accounts

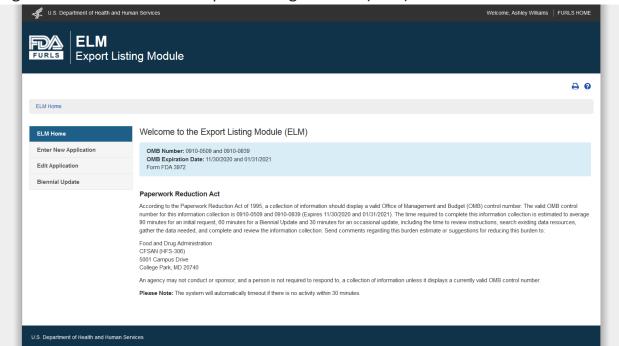
On the Create New Account screen, under the Registration and Listing Programs select Export Listing Module as one of the systems you will need to access. You may select additional systems if you wish. If you need detailed instructions for creating a new account, please visit <a href="Create New Account Step-by-Step">Create New Account Step-by-Step</a> <a href="Instructions">Instructions</a>. Once you have created an account and logged in, you will see the online account administration page for FDA Industry Systems.

Figure 3: Accessing the ELM



To access the Export Listing Module, log in to the FDA Industry Systems. Under Registration and Listing Programs, select Export Listing Module (ELM).

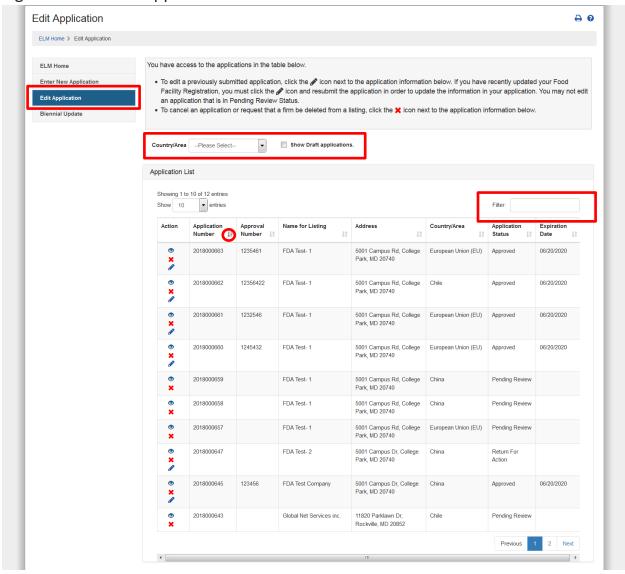
Figure 4: Welcome to the Export Listing Module (ELM)



After clicking on the ELM, you will reach the Export Listing Module welcome page. The menu on the left side of the screen provides the following options: Enter New Application, Edit Application, and Biennial Update.

## **Edit Application**

Figure 5: ELM Edit Application Dashboard

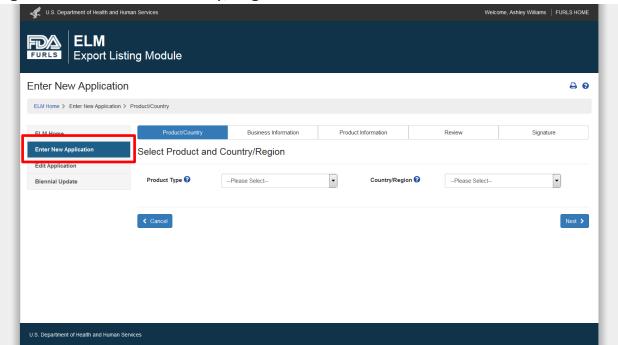


To view a list of the applications associated with your account, select "Edit Application" from the menu on the left side of the screen. You may search for applications by entering key words in the filter text box or by using the sort button in each category column.

- Select the eye icon in the action column to view the application.
- Select the pencil icon in the action column to edit the application. This will allow you to change
  any editable fields in the application. Please note that you must click through all the screens and
  resubmit your application in order for your changes to take effect.
- Select the red "X" button to request to delete an application. Please note that the ELM will only allow one application for a facility. If you delete an application with an Application Status of "Approved", it will be removed from the export list. Once you confirm your delete request, you will not be able to edit your deleted application.

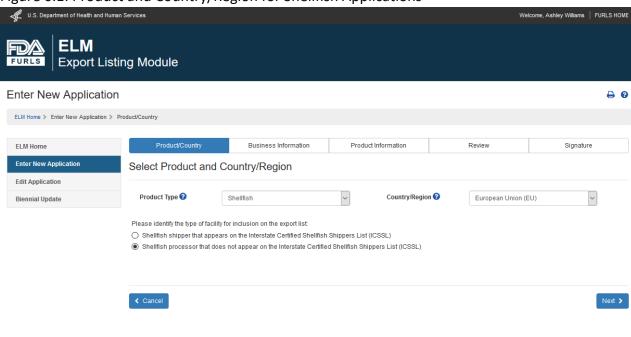
# **Enter New Application**

Figure 6: Product and Country/Region



To request to be added to an export list, select "Enter New Application" from the menu on the left side of the screen. You will be prompted to identify the Product Type and Country/Region of the export list for which you wish to apply. After making your selection, click the blue "Next" button at the bottom of the screen to proceed with the application.

Figure 6.1: Product and Country/Region for Shellfish Applications



U.S. Department of Health and Human Services

If you select Shellfish as the Product Type, you will be prompted to answer an additional question about the type of facility for inclusion on the export list. After making your selection, click the blue "Next" button at the bottom of the screen to proceed with the application.

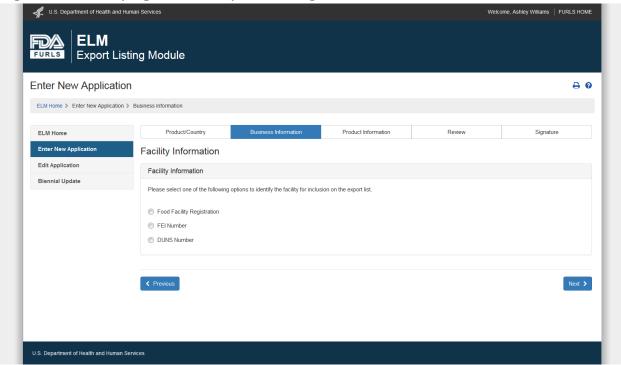


Figure 7: Identifying the Facility for Listing

For most applications, you may identify the facility for listing by entering a DUNS number, a FDA Establishment Identifier (FEI), or by selecting a food facility associated with your FIS/OAA account. For shellfish facilities that are included on the Interstate Certified Shellfish Shippers List (ICSSL), please see Figure 7.1 State and Certificate Information.

The ELM will auto-populate your name and address for listing from FDA records based on the way that you identify the facility. Please note: The best option is to use the Food Facility Registration, which allows you to have complete control over the name and address that gets populated on your ELM application.

You may visit <a href="https://fdadunslookup.com/">https://fdadunslookup.com/</a> to search for or request a valid DUNS number. Note: DUNS numbers contain 9 digits. If your DUNS number contains a leading zero (i.e., a zero as the first digit), you must enter that zero to find the record(s) for your facility.

ELM Export Listing Module

Enter New Application

EM Home > Enter New Application > Suchees information

ELM Home | Product/Country | Business information | Product Information | Review | Signature |

Ester New Application | State and Certificate Information | Product Information | Review | Signature |

Ester New Application | State and Certificate Information | Prease State and Certificate Information |

Edit Application | Prease State in which the shallful hold half and the certificate number as identified on the Inferstate Certified Shallful Shippers List |

1015 (Previous | Prease State | Prease

Figure 7.1: State and Certificate Information for Shellfish Facilities on the ICSSL

Shellfish facilities that are included on the Interstate Certified Shellfish Shippers List (ICSSL) will be prompted to enter the state where the facility is located and the certificate number from the ICSSL.

You may visit <a href="https://www.accessdata.fda.gov/scripts/shellfish/sh/shellfish.cfm">https://www.accessdata.fda.gov/scripts/shellfish/sh/shellfish.cfm</a> to search for your certificate number. Note: If your ICSSL certificate number contains one or more multiple leading zeroes (e.g., a zero as the first digit), you must enter those zeroes to find the record for your facility.

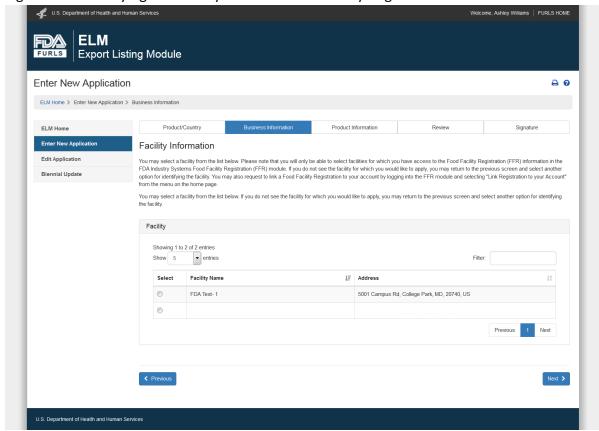
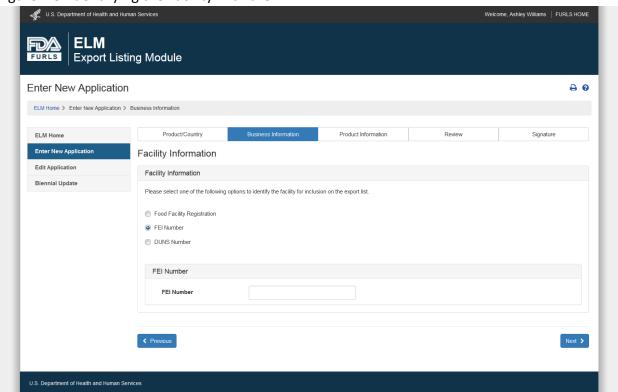


Figure 7.2: Identifying the Facility with the Food Facility Registration

If you choose to identify the facility for listing by the Food Facility Registration, the system will display a list of all registered food facilities associated with your FDA Industry Systems account. Select the correct facility for your application and click the blue "Next" button at the bottom of the screen to proceed with the application.

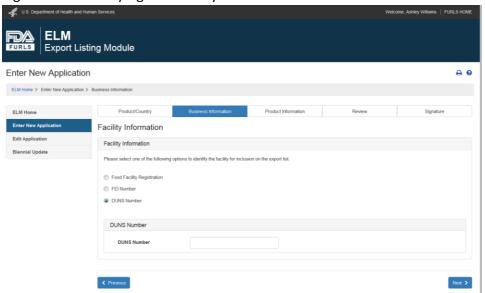
If you represent a food facility, but do not see an option to identify this facility by the Food Facility Registration, you may associate this facility with your account if you have the facility's Food Facility Registration number and PIN. To do this, click on the "Food Facility Registration" link from the FURLS/FIS home page. Once the Food Facility Registration module opens, select "Link Registration to your Account" on the left side of the screen and enter the facility's Food Facility Registration number and PIN.

Figure 7.3: Identifying the Facility with the FEI



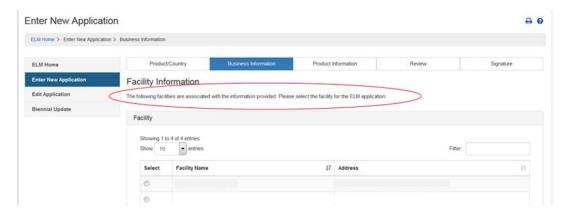
If you choose to identify the manufacturer by FEI number, enter the FEI number and click the blue "Next" button at the bottom of the screen to proceed with the application. If you receive an error message, please contact CFSANExportCertification@fda.hhs.gov for assistance.

Figure 7.4: Identifying the Facility with the DUNS



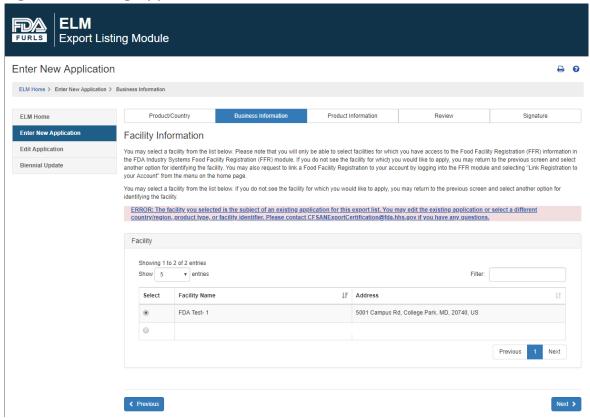
If you choose to identify the manufacturer by DUNS number, enter the DUNS number and click Next.

You may visit https://fdadunslookup.com/ to search for or request a valid DUNS number.



If there are multiple facilities associated with the DUNS number, you will have the option to select the correct name and address. If there are multiple records with the same or similar names/addresses, you may contact <a href="mailto:CFSANExportCertification@fda.hhs.gov">CFSANExportCertification@fda.hhs.gov</a> for assistance in choosing the correct record. Click the blue "Next" button at the bottom of the screen to proceed with the application.

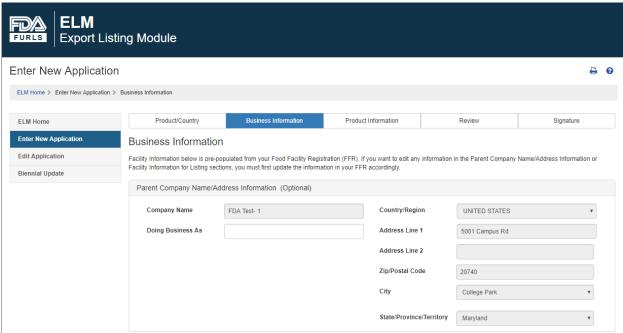
Figure 8: Existing Application Error



The system will not allow you to submit a duplicate application for a facility for the same product type and country/region. You will see an error message if you try to select a facility for which there is already an application for the product type and country/region.

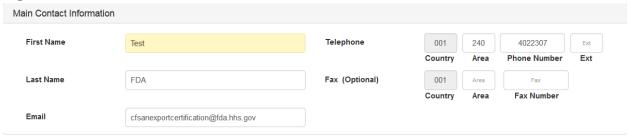
If you receive this error message, please contact CFSANExportCertification@fda.hhs.gov for assistance.

Figure 9: Parent Company Name/Address Information



After you have identified the facility, the Business Information page will display. If you identified the facility using a Food Facility Registration, this section is prepopulated from the Parent Company section of the Food Facility Registration (FFR) module. If you identified the facility using an FEI number or a DUNS number, this section is not prepopulated and you may optionally enter this information. The Doing Business As field is optional regardless of how you identify the facility.

Figure 10: Main Contact Information



The Main Contact Information is prepopulated from your FDA Industry Systems account. You may edit this information if needed. Notifications about this application will be sent to this email address.

## **Facility Information for Listing**

Figure 11: Facilities Identified by FFR

cility Information for L	isting and Address will be used for the Countr	v.l.iet		
Facility Type	Processing Plant	y List.	Facility Street Address Line 1	5001 Campus Rd
Name for Listing	FDA Test- 1	<u>\</u>	Facility Street Address Line 2 (Optional)	
			Zip/Postal Code	20740
			City	College Park
			State/Territory	Maryland

#### **Facility Type**

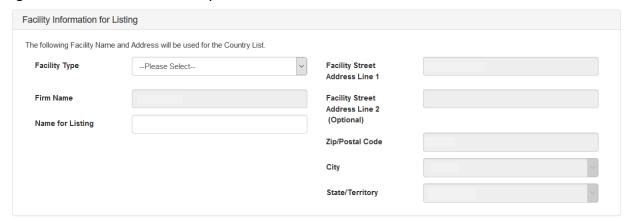
You must select a "Facility Type" from the dropdown menu. The facility type selected will be reflected on the export list.

## Name and Address for Listing

If your application is approved, the "Name for Listing" and the address in this section will be included on the export list. Please confirm that these fields are accurate before proceeding with the application.

If you identified the facility using a Food Facility Registration, the address for listing will be prepopulated with the Facility Address from the Food Facility Registration (FFR) module. If you want to edit the facility address for listing, you must first update the address in your FFR accordingly. You will have the option of selecting any name associated with your FFR as the "Name for Listing". If you do not see the name with which you wish to be listed, you may update your FFR to edit an existing name in the FFR or provide an "Alternate Trade Name". If you need to edit your FFR, save the ELM application as a draft and exit the application, then update your FFR and return to the ELM to finish your draft application.

Figure 12: Facilities Identified by FEI or DUNS



#### **Facility Type**

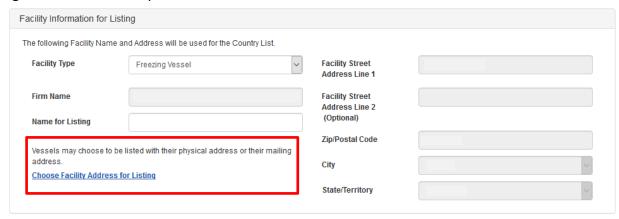
You must select a "Facility Type" from the dropdown menu. The facility type selected will be reflected on the export list.

#### Name and Address for Listing

If your application is approved, the "Name for Listing" and the address in this section will be included on the export list. Please confirm that these fields are accurate before proceeding with the application.

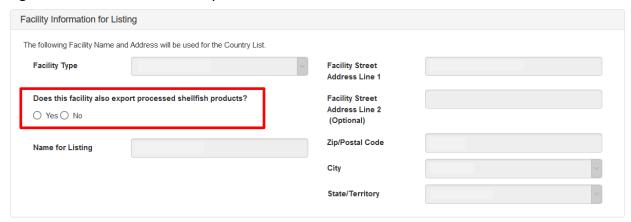
If you identified the facility using a FEI or a DUNS number, the address for listing will be prepopulated with the physical address that FDA has on record for your facility and the "Firm Name" and "Name for Listing" field will be prepopulated with the legal firm name that FDA has on record for your facility. You may edit the "Name for Listing" field if you wish to be listed by another name.

Figure 12.1: Address Options for Seafood Vessels



If you select freezing vessel or factory vessel as the facility type, you will have the ability choose to be listed with their facility's physical address or their mailing address. Click on the link 'Choose Facility Address for Listing' and make your selection for listing.

Figure 13: Facilities Identified by ICSSL Certificate Number



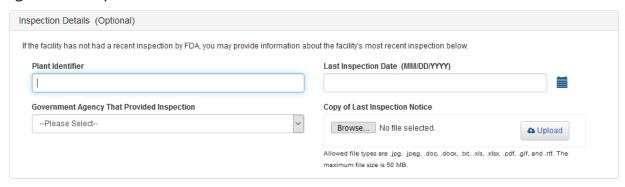
## **Facility Type**

For shellfish facilities on the ICSSL, the facility type is automatically populated based on the ICSSL activities for which the facility is certified. You must indicate whether the facility also exports processed shellfish products.

## Name and Address for Listing

The name and address for listing are prepopulated from the ICSSL.

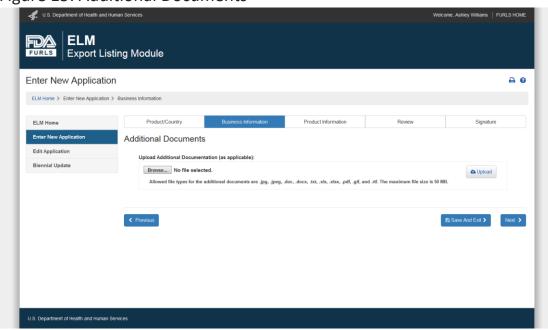
Figure 14: Inspection Details



The Inspection Details section is optional. You may enter your plant identifier, select the last type of inspection that was conducted at the manufacturer's facility. Enter the date the inspection was completed and upload an inspection notice (i.e., report of inspection findings). If your facility has been inspected by FDA, you do not need to complete this section. If your facility has not been inspected by FDA, providing the details for your most recent inspection will prevent delays in the application review process.

Select the "Browse" button to upload an inspection notice. This document must clearly identify the name and address of the facility for which you are applying, the inspecting agency, the purpose of the inspection, and the inspection result. You may attach a document in jpeg., jpg, doc., docx., txt., xls., pdf., gif., and rtf format. After you have selected the document, click the "Upload" button. If the document was successfully uploaded, you will see a confirmation message. Select the "Next" button to move forward in the application.

Figure 15: Additional Documents



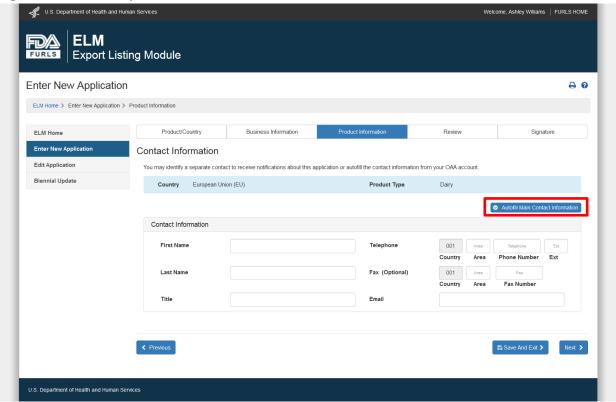
You may upload additional documents for review. To upload additional documents, select the browse button. You may attach a document in jpg., jpeg., doc., docx., txt., xls., xlsx., pdf., gif., and rtf format. After you have selected the document, click the "Upload" button. You will see a confirmation message if the document was successfully uploaded.

For firms exporting to China, you may upload an audit letter or other evidence of third-party certification here.

For Collagen and Gelatin applications, you may upload your laboratory results here. Establishments must provide a laboratory report from an accredited, private laboratory demonstrating that the products for export do not exceed the following criteria:

- Total aerobic bacteria –103/g
- Coliforms (30°C) 0/g
- Coliforms (44.5°C) 0/10g
- Anaerobic sulphite-reducing bacteria (no gas production) -10 /g
- Clostridium perfringens 0/g
- Staphylococcus aureus 0/g
- Salmonella 0/25g
- As 1 ppm
- Pb 5 ppm
- Cd 0,5 ppm
- Hg 0,15 ppm
- Cr 10 ppm
- Cu 30 ppm
- Zn 50 ppm
- SO2- 50 ppm
- H2O2 10 ppm

Figure 16: Country Contact Information



You may identify an additional contact to receive updates about the application. If you do not wish to identify an additional contact, select the "Autofill Main Contact Information" button. Select "Next" to proceed with the application.

The fields on the product information screen will vary depending on the product type and country/region selected.

Figure 17: Dairy EU Product Information

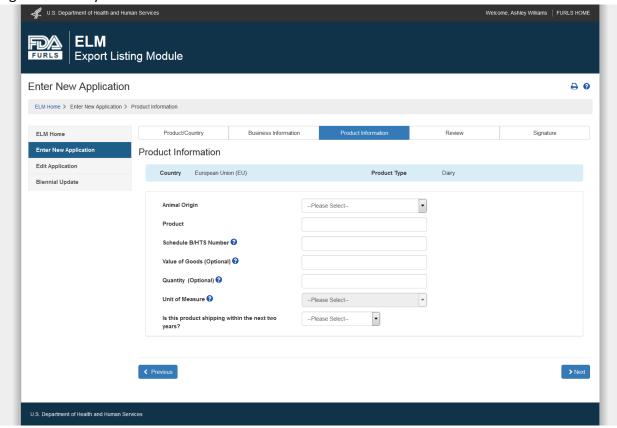
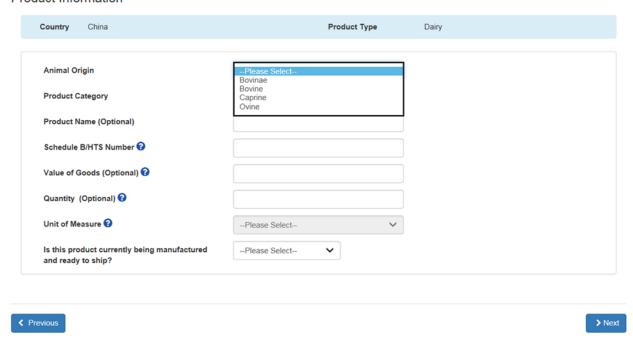


Figure 18: Dairy China Product Information Product Information



Please enter all required information. Select from the product category dropdown the option that best describes your product. If you have question regarding the product category please reference the <u>AQSIQ Implementation Catalogue</u>. Select "Next" to proceed with application.

Figure 19: Dairy Chile Product Information

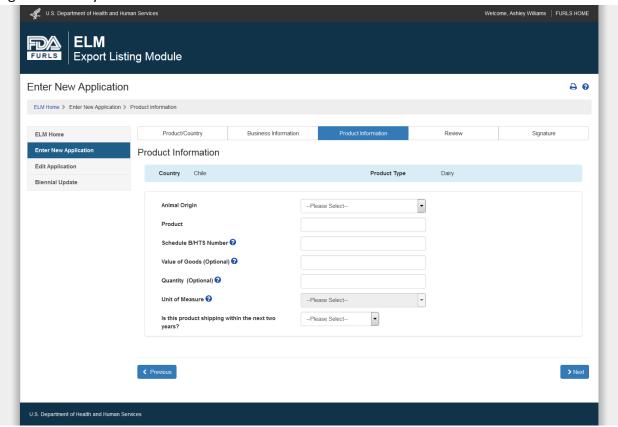


Figure 20: Seafood China Product Information

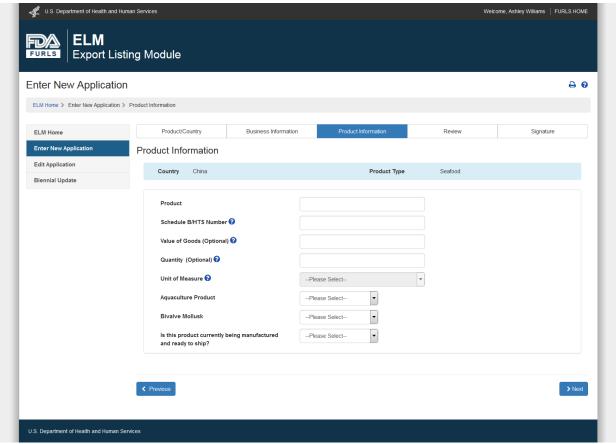


Figure 21: Seafood EU Product Information

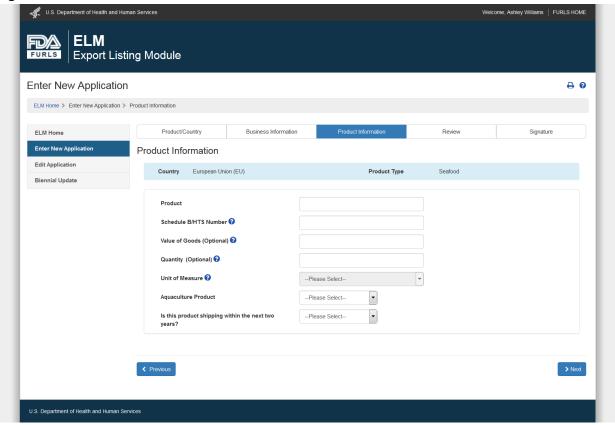


Figure 22: Shellfish EU Product Information

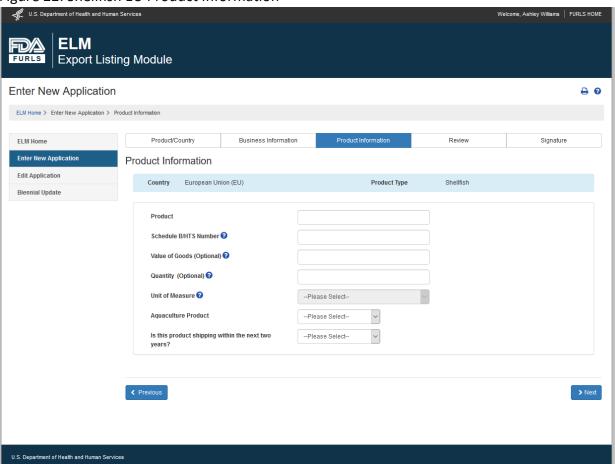
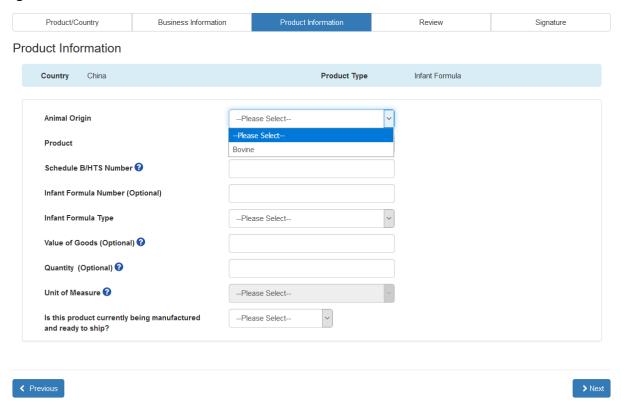


Figure 23: Infant Formula China Product Information



Please enter all required information. The Infant Formula Number (IFN) is required for review of the export list application. Please reference the <u>AQSIQ Implementation Catalogue</u> for questions regarding the Infant Formula Type. Select "Next" to proceed with application.

Figure 24: Collagen EU Product Information

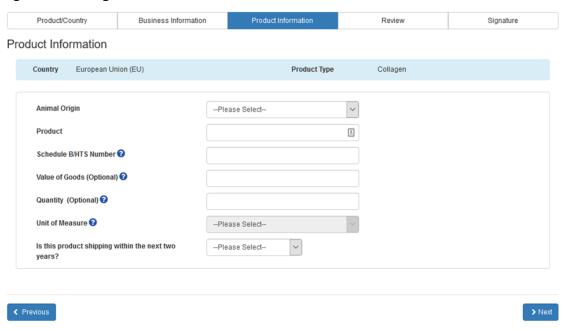


Figure 24.1: Fish Collagen EU Product Information

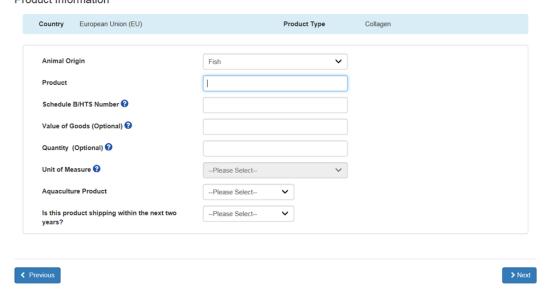


Figure 25: Gelatin EU Product Information

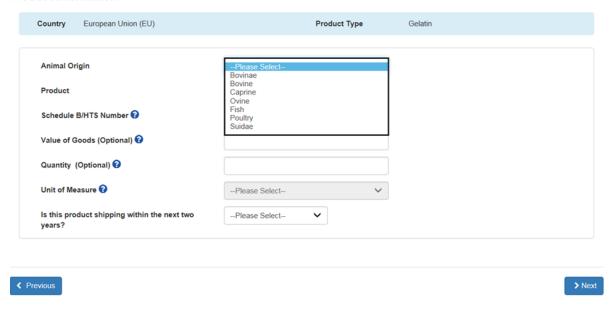


Figure 25.1: Fish Gelatin EU Product Information

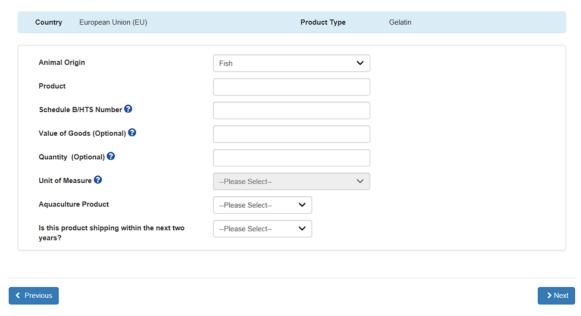
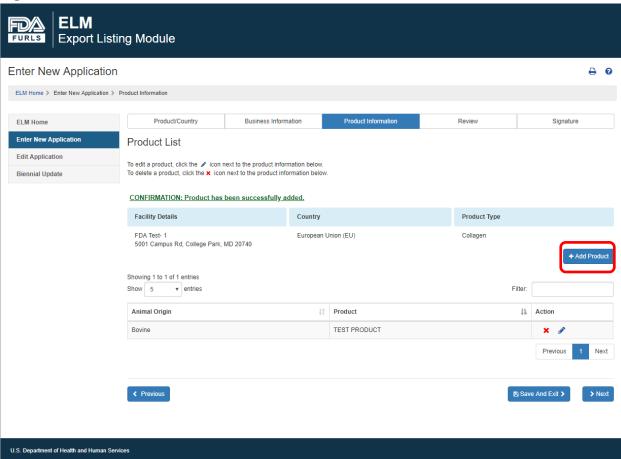
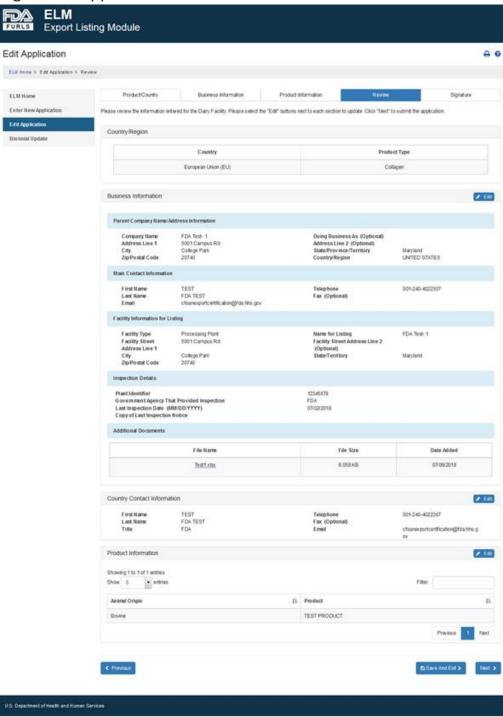


Figure 26: Product List



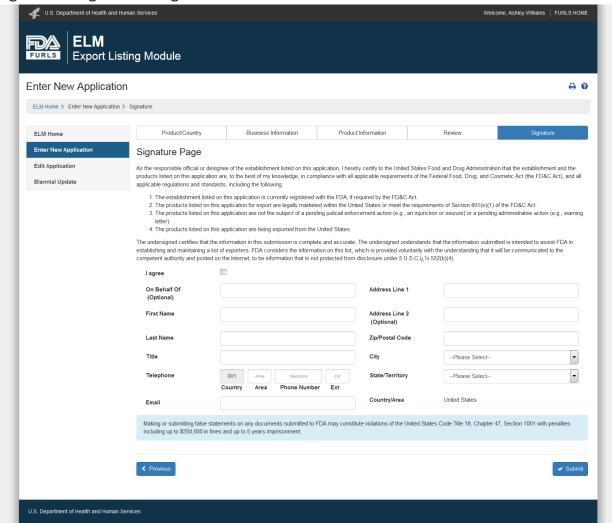
The Product List page will display all the products associated with the application. Select the "Next" button to proceed with the application. To add additional products to your application, select the "+Add Product" button.

Figure 27: Application Review



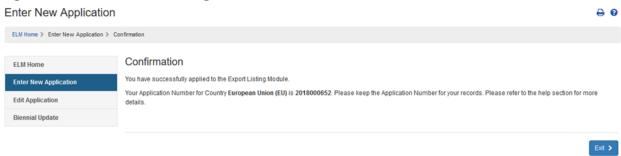
The application review page will display all entered information. You may revise each section by selecting the edit button. After reviewing, select the "Next" button to proceed with the application.

Figure 28: Signature Page



Enter all required fields on the Signature Page. Select the "Submit" button to submit the application for processing.

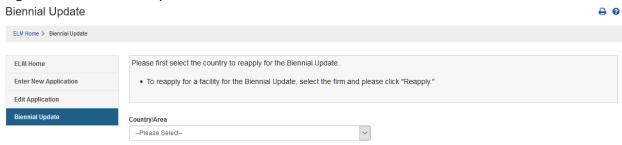
Figure 29: Confirmation Page



After submission, a confirmation page will display your application number. Please keep this number for future inquiries about your application.

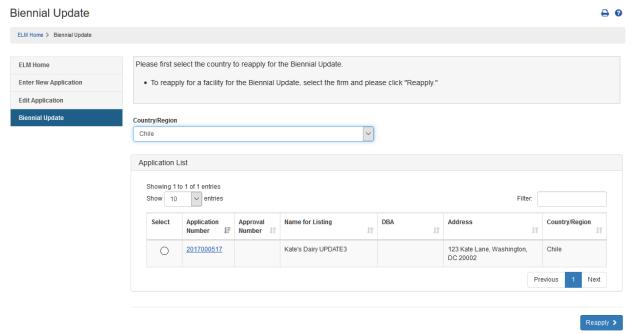
# **Biennial Update**

## Figure 30: Biennial Update



To view all applications that require an update, select "Biennial Update" from the menu on the left side of the screen. You will be prompted to select a country/area.

Figure 31: Biennial Update List of Applications



The system will display all applications for the selected country/area. Select the radio button for the application for which you wish to submit a biennial update and click the blue "Reapply" button to continue. Confirm the information on each page of the application before submitting.